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# 1.0 Description of the Procedure

A cochlear implant device is an electronic instrument, part of which is implanted surgically into the cochlea to stimulate auditory nerve fibers and part of which is capable of detecting and codifying sound for neural stimulation and is worn or carried by the individual. The goal of implantation is to enable an awareness of sound, identification of sounds, and facilitation of auditory/oral communication for individuals with severe to profound sensorineural hearing loss.

An auditory brainstem implant (ABI) is a modification of the cochlear implant in which the stimulating electrode is placed directly into the brain.

After surgery, these two devices require activation, fitting of essential external components, programming, and rehabilitation for proper function and benefit.

# 2.0 Eligible Recipients

## 2.1 General Provisions

Medicaid recipients may have service restrictions due to their eligibility category that would make them ineligible for this service.

## 2.2 EPSDT Special Provision: Exception to Policy Limitations for Recipients under 21 Years of Age

**42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]**

Early Periodic Screening, Diagnostic and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid recipients under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination****** (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the recipient's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the recipient's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

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Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

****EPSDT and Prior Approval Requirements**

a. If the service, product, or procedure requires prior approval, the fact that the recipient is under 21 years of age does **NOT** eliminate the requirement for prior approval.

b. IMPORTANT ADDITIONAL INFORMATION about EPSDT and prior approval is found in the Basic Medicaid Billing Guide, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

***Basic Medicaid Billing Guide*:** http://www.ncdhhs.gov/dma/medbillcaguide.htm

**EPSDT provider page:** http://www.ncdhhs.gov/dma/EPSDTprovider.htm

## 3.0 When the Procedure Is Covered

**IMPORTANT NOTE:** EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

**EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED.** For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy.

### 3.1 General Criteria

Medicaid covers cochlear and auditory brainstem implants when they are medically necessary **and**

a. the procedure is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;

b. the procedure can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and

c. the procedure is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

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## 3.2 Specific Criteria

### 3.2.1 Cochlear Implant

Cochlear implants and aural rehabilitation are covered for recipients ages 12 months through 20 years of age when **all** of the following criteria are documented in the medical record.

a. The recipient

(1) has the confirmed ~~a~~ diagnosis of bilateral profound (>90 dB HL) sensorineural hearing loss

(2) has limited benefit from at least a 3-month hearing aid~~s~~ trial. When radiological evidence of on-going cochlear ossification or obstruction exists, the trial requirement can be waived.

Note: For older children, limited benefit from amplification is defined by ~~a~~ test score~~s~~ of less than or equal to 40% correct in the best-aided listening condition on age appropriate tests of open-set speech perception.

(3) is free of middle ear infection, has an accessible cochlear lumen that is structurally sound for implantation, and is free of lesions of the central auditory pathway from the brainstem and higher.

b. The device must be approved by the Food and Drug Administration (FDA), and must be used in accordance with FDA labeling.

c. There are no contraindications for the surgery.

d. The personal physician or otolaryngologist documents that the recipient has realistic expectations of the performance of the device and is able to participate in the required postoperative therapy, training, and rehabilitation.

### 3.2.2 Auditory Brainstem Implants

ABIs are covered when **all** of the following criteria are met. Refer to **Section 5.1.2** for prior approval requirements.

a. The recipient is 12 years through 20 years of age.

b. The recipient has been diagnosed with neurofibromatosis type 2.

c. The recipient

1. is undergoing bilateral removal of tumors of the auditory nerves, and it is anticipated that the recipient will become completely deaf as a result of the surgery; **or**

2. has had bilateral auditory nerve tumors removed and is now bilaterally deaf.

d. The device must be approved by the FDA, and must be used in accordance with FDA labeling.

e. There are no contraindications for the surgery.

## 3.3 Upgrades and Maintenance

Refer to **Section 5.1.3** for prior approval requirements.

Medically necessary maintenance and upgrades of existing internal components for next-generation devices are covered for recipients aged 12 months and older when

a. the recipient's response to existing components is inadequate to the point of interfering with the activities of daily living; **or**

b. the components are no longer functional.

**Note:** Upgrades to existing, functioning external systems to achieve aesthetic improvement—such as substituting smaller-profile components or switching from a body-worn external sound processor to a behind-the-ear model—are not medically necessary and will not be covered.

For information on requirements and limitations for external components, refer to Clinical Coverage Policy # 1A-4-2, *Cochlear and Auditory Brainstem Implant External Parts Replacement and Repair* on DMA's Web site at http://www.ncdhhs.gov/dma/mp/mpindex.htm

## 3.4 Contralateral Cochlear Implant

Coverage of contralateral cochlear implant after the successful placement of the original implant is considered on a case-by-case basis for recipients aged 12 months through 20 years and must be supported by documentation of medical necessity. Refer to **Section 5.1.4** for information on prior approval for contralateral implants.

Contralateral implants are covered, after the implantation of the **first side** device, when all of the following are met:

a. demonstrated successful usage of the device **and**

a. active participation in an appropriate auditory-based intervention program **and**

b. active participation in an appropriate educational program **and**

c. radiographic evidence that contralateral cochlea and nerves are normal **and**

d. demonstration by the patient and/or family of an ability to care for the equipment needs of 2 devices **and**

e. no evidence of severe physical, psychomotor, or cognitive delays **and**

f. when at least one of the following applies:

1. continued usage of a hearing aid has been unsuccessful, if residual hearing is present or
2. the first side device is non-functional for medical/surgical reasons and replacement surgery is not an option or
3. the first side is suspected of having a device failure but still provides some beneficial auditory input or
4. the recipient develops significant delayed-onset visual impairment

## 3.5 Simultaneous Bilateral Cochlear Implants

Refer to **Section 5.1.5** for prior approval requirements.

Simultaneous bilateral cochlear implants are covered only when there is

a. clear evidence of ongoing bilateral cochlear ossification or fibrosis from previous meningitis or cochlear inflammation **or**

b. significant bilateral visual impairment present or expected to develop, such as in Usher's syndrome.

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### 3.6 Diagnostic Analysis and Programming

Activation, evaluation, and programming of the cochlear and auditory brainstem implants are covered as separate procedures for recipients aged 12 months and older after the post-operative period. Refer to **Section 5.2** for additional information on diagnostic analysis and programming.

## 4.0 When the Procedure Is Not Covered

**IMPORTANT NOTE:** EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

**EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED.** For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy.

### 4.1 General Criteria

Cochlear and auditory brainstem implants are not covered when

a. the recipient does not meet the eligibility requirements listed in **Section 2.0;**
b. the recipient does not meet the medical necessity criteria listed in **Section 3.0;**
c. the procedure unnecessarily duplicates another provider's procedure; or
d. the procedure is experimental, investigational, or part of a clinical trial.

### 4.2 Specific Criteria

a. A cochlear implant is contraindicated for the following conditions:
    1. Deafness due to lesions of the central auditory pathway
    2. Otitis media or other active, unresolved ear problems
    3. Radiographic evidence of absent cochlear development
b. N.C. Medicaid does not cover bilateral cochlear implants during the same or subsequent operative session except when the criteria outlined in **Section 3.5** are met.

## 5.0 Requirements for and Limitations on Coverage

**IMPORTANT NOTE:** EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

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**EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED.** For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy.

## 5.1 Prior Approval

### 5.1.1 Cochlear Implant

Prior approval is not required for routine, unilateral cochlear implantation that meets the criteria in **Section 3.2.**

### 5.1.2 Auditory Brainstem Implant

Prior approval is required. Medical record documentation must be submitted with the prior approval request indicating that the recipient

a. is 12 years through 20 years of age; **and**
b. has been diagnosed with neurofibromatosis type 2; **and**
c. is undergoing bilateral removal of tumors of the auditory nerves, and it is anticipated that the recipient will become completely deaf as a result of the surgery; **or**
d. has had bilateral auditory nerve tumors removed and is now bilaterally deaf.

### 5.1.3 Upgrades and Maintenance

Prior approval is required for the upgrade and maintenance of internal components. Medical record documentation must be submitted with the prior approval request indicating that

a. the recipient's response to the existing component(s) is inadequate to the point of interfering with the activities of daily living; **or**
b. the component(s) are no longer functional.

### 5.1.4 Contralateral Cochlear Implant

Prior approval is required for a contralateral cochlear implant. The prior approval request must include the following documentation:

a. the date of the initial placement of a cochlear implant; **and**
b. the successful aural rehabilitation and use of the current implant; **and**
c. why a contralateral implant is medically necessary, as outlined in **Section 3.4.**

### 5.1.5 Simultaneous Bilateral Cochlear Implants

Prior approval is required. Medical record documentation must be submitted with the prior approval request indicating that the requirements of **Section 3.5** have been met.

### 5.1.6 Aural Rehabilitation

Prior approval is required. Refer to Clinical Coverage Policy #10A, *Outpatient Specialized Therapies,* for additional information.

## 5.2 Diagnostic Analysis and Programming

Postoperative diagnostic analysis and programming of the cochlear and auditory brainstem implants do not require prior approval. Medical record documentation should include the date of the surgery and status of the analysis and programming procedures.

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### 5.3 Replacement Parts and Repairs

Coverage requirements and limitations for replacement parts and repairs to cochlear and auditory brainstem implants are documented in Clinical Coverage Policy #1A-4-2, on DMA's Web site at http://www.ncdhhs.gov/dma/mp/mpindex.htm.

## 6.0 Providers Eligible to Bill for the Procedure

Physicians enrolled in the N.C. Medicaid program who perform this surgery may bill for this service when it is within the scope of their practice.

## 7.0 Additional Requirements

### 7.1 Records Retention

All records related to the placement of cochlear and auditory brainstem implants should be maintained through the life of the implant and, at a minimum, for not less than five years.

As a condition of participation, providers are required to keep records necessary to disclose the extent of services rendered to recipients and billed to the N.C. Medicaid program [Social Security Act 1902(a)(27) and 42 CFR 431.107]. Records must be retained for a period of at least five years from the date of service, unless a longer retention period is required by applicable federal or state law, regulations, or agreements (10A NCAC 22F.0107).

Copies of records must be furnished upon request.

The Health Insurance Portability and Accountability Act (HIPAA) does not prohibit the release of records to Medicaid (45 CFR 164.502).

### 7.2 Federal and State Requirements

All providers must comply with all applicable federal and state regulations and laws.

## 8.0 Policy Implementation/Revision Information

**Original Effective Date:** September 1, 1998

**Revision Information:**

| Date | Section Updated | Change |
|---|---|---|
| | | |
| | | |

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# Attachment A: Claims-Related Information

Reimbursement requires compliance with all Medicaid guidelines, including obtaining appropriate referrals for recipients enrolled in Medicaid managed care programs.

## A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

## B. Diagnosis Codes that Support Medical Necessity

Providers must bill the ICD-9-CM diagnosis code(s) to the highest level of specificity that supports medical necessity. Diagnoses that support medical necessity for the cochlear implant include 389.10 and 389.18. The diagnosis that supports medical necessity for the ABI is 237.72.

## C. Procedure Codes

**Physicians**

| Code | Description | Purpose |
|---|---|---|
| 69930 | Cochlear device implantation, with or without mastoidectomy | Implantation of the cochlear device |
| S2235 | Implantation of auditory brain stem implant | Implantation of the ABI device |
| 69949 | Unlisted procedure, inner ear | Upgrades |
| 92601 | Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming | Initial postoperative fitting, analysis and programming of the cochlear implant, recipient less than 7 years old. |
| 92602 | Diagnostic analysis of cochlear implant, patient younger than 7 years of age; subsequent reprogramming | Subsequent analysis and reprogramming of the cochlear implant, recipient less than 7 years old. |
| 92603 | Diagnostic analysis of cochlear implant, age 7 years or older; with programming | Initial postoperative fitting, analysis and programming of the cochlear implant, recipient 7 years of age or older. |
| 92604 | Diagnostic analysis of cochlear implant, age 7 years or older; subsequent reprogramming | Subsequent analysis and reprogramming of the cochlear implant, recipient 7 years of age or older. |
| 92640 | Diagnostic analysis with programming of auditory brainstem implant, per hour | Postoperative analysis and programming of the auditory brainstem implant. |

Aural rehabilitation is billed according to the guidelines listed in Clinical Coverage Policy #10A, *Outpatient Specialized Therapies.*

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**Hospitals**

| Code | Description | Purpose |
|---|---|---|
| RC 278 | Medical/surgical supplies and devices—other implant | Cochlear implant device<br>ABI device |

## D. Modifiers

Providers are required to follow applicable modifier guidelines.

Simultaneous bilateral cochlear implants are billed with 69930 and modifier 50.

## E. Place of Service

Inpatient, outpatient

## F. Reimbursement Rate

Providers must bill their usual and customary charges.

## G. Co-Payments

Co-payments are not deducted for services provided to recipients less than 21 years of age.

## H. Billing Units

The procedure codes documented in Section C are billed with one unit, except for CPT code 92640, which is billed as 1 unit = 1 hour.